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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,778	10/29/2003	Jeffrey M. Sieracki	1023-229US01	6900
28863	7590	12/30/2005	EXAMINER	
SHUMAKER & SIEFFERT, P. A.			ROBERTS, DARIN	
8425 SEASONS PARKWAY			ART UNIT	
SUITE 105			PAPER NUMBER	
ST. PAUL, MN 55125			3762	

DATE MAILED: 12/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/696,778	Applicant(s) SIERACKI ET AL.	
	Examiner Darin R. Roberts	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 10, 12, 13, 15-22, 26, 28, 29, 31-33, 35-37, 41, 45-48 and 50 is/are rejected.
- 7) ☒ Claim(s) 7-9, 11, 14, 23-25, 27, 30, 34, 38-40, 42-44 and 49 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/12/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities:

- The first sentence of paragraph [0007] should be changed to “The filter information may, for example, identify a number of electrodes for valid electrode combinations, identify a fixed polarity of one or more of the electrodes of the electrode set for valid electrode combinations, and/or identify a relational characteristic, e.g., a contiguous or guarded electrode ...”
- The second sentence of paragraph [0021] should be changed to “System 10 includes an implantable medical device (IMD) 14 that delivers ...”
- Within the last sentence of paragraph [0042] the *filter information* is associated with reference number “58” and the configuration information is associated with reference number “56”, however throughout the majority of the disclosure and within the drawings the *filter information* is commonly associated with reference number “56” and the configuration information is commonly associated with reference number “56”.
- Within the first sentence of paragraph [0051] the *filter information* is associated with reference number “58”, however the *filter information* is

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commonly associated with reference number "56" through out the majority of the disclosure and with the drawings.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The preamble of claim 32 is directed toward a computer readable medium, while the latter portion of the claim is directed toward implantable electrodes, there appears to be no connection between the two devices.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, & 16 are rejected under 35 U.S.C. 102(e) as being anticipated by McClure (US 6659968 B1).

In reference to **claims 1-4**, the McClure (US 6659968 B1) patent teaches the comparison of data (see col. 7, lead Ins. 38-41) as well as the "Various stimulation parameter sets are available for execution once a permanent implantable stimulator is in place. Such stimulation parameter sets define various waveforms and electrode combinations. The ability to evaluate the

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effectiveness of a multiplicity of stimulation parameter sets, over a long period of time, permits a clinician to determine the best overall stimulation parameter set for a patient" (see col. 3 lns. 14-20). The McClure patent also teaches that "the output of the sensor is filtered to pass data associated with defined activities, and processed to measure the level of activity of a patient ... the activity monitor provides feedback to an update stimulation parameters function to enable long term tuning of stimulation parameters" (see col. 2, lns. 60-63 & col. 3, lns 1-3).

In reference to **claim 16**, the ability to implant an implantable device is a function that is inherent to the claimed device.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5, 6, 10, 12, 13, 15, 17-22, 26, 28, 29, 31, 33, 35, 36, 37, 41, 45
are rejected under 35 U.S.C. 103(a) as being unpatentable over McClure (US 6659968 B1) in view of Woods et al. (US 6609032 B1).

In reference to **claims 5, 6, 36, & 37**, McClure teaches the use electrodes to provide spinal cord stimulation, however McClure does not teach the use of

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filter information to identify a fixed polarity of one of the electrodes of the electrode set. The Woods et al. patent teaches a “stimulator processor 52 takes the pulse characterization data, as well as the electrode group data, and processes such data so that the appropriate commands can be sent to the implantable receiver 20” such a process can be seen as a form of filtration (see col. 12, Ins. 15-18). The Woods et al. patent also teaches an “implantable stimulator 20 then acts on the data received so as to provide the programmed stimulation currents to the group of electrodes selected by the directional device 12 and selectors 42, using the polarity defined by the received data” (see col. 12, Ins. 30-33).

Thus it would have been obvious to one of ordinary skill in the art to combine the aforementioned aspects of the McClure patent with the filtration and stimulation aspects of the Woods et al. patent to provide the wearer with the appropriate stimulation parameters.

In reference to **claims 10, 13, 15, 41 & 45**, the McClure patent does not teach a list of electrodes, however the Woods et al. patent does teach “various programmable features or functions associated with the programmer system may be selected using the keys. Once selected, a ‘store’ button is provided to allow a desired electrode configuration, including other selected parameters, or a desired function, to be selected and saved in memory so that it can be recalled as desired to define the electrode configuration to be used at a later date” (see col. 9, Ins. 32-39).

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In reference to **claims 12, & 46**, the McClure patent does not teach that a clinician would handle the device however it would be obvious to one of ordinary skill in the art to have a trained professional in the art handle the device.

In reference to **claims 17-22, 26, 28, 29, & 31**, McClure does not teach the placement of instructions onto a computer readable medium, however, the placement of instructions for an electronic device on to a computer readable medium would have been obvious to one of ordinary skill in the art.

In reference to **claims 33, 35 & 48**, The McClure patent does not teach the use of a user interface however the McClure patent does teach the comparison of data (see col. 7, lead Ins. 38-41) as well as the "Various stimulation parameter sets are available for execution once a permanent implantable stimulator is in place. Such stimulation parameter sets define various waveforms and electrode combinations. The ability to evaluate the effectiveness of a multiplicity of stimulation parameter sets, over a long period of time, permits a clinician to determine the best overall stimulation parameter set for a patient" (see col. 3 Ins. 14-20). The McClure patent also teaches that "the output of the sensor is filtered to pass data associated with defined activities, and processed to measure the level of activity of a patient ... the activity monitor provides feedback to an update stimulation parameters function to enable long term tuning of stimulation parameters" (see col. 2, Ins. 60-63 & col. 3, Ins 1-3).

The Woods patent does teach the use user interface (see col. 9, Ins. 32-39).

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This it would have been obvious to one of ordinary skill in the art to combine the aforementioned aspects of the McClure patent with the user interface of the Woods patent to provide the user with a means for adjusting the level of stimulation.

In reference to **claims 47 & 50**, the presence of a programming device within an implantable stimulator and the implantation of implantable electrodes is quite common in the art, thus the use of a programming device and the implantation of implantable electrodes would have been obvious to one of ordinary skill in the art.

In reference to claim 7, the McClure patent does not teach the setting the polarities of the electrodes, however the Woods et al. patent does teach a "system and a method for programming that allows a clinician or patient to quickly determine a desired electrode stimulation pattern, including which electrodes of a multiplicity of electrodes in an electrode array should receive a stimulation current, the polarity, distance between anodes and cathodes, and distribution of stimulation intensity or amplitude ..." (see col. 6, Ins. 41-48). The Woods et al. patent also teaches an invention that provides "an electrode selection system that allows the user (the person operating the programmer) to readily select and visualize a particular group of electrodes of an electrode array for receipt of a stimulation pulse current, and when selected to allow different combinations of pulse amplitude, pulse width, pulse repetition rate, or other pulse-defining parameters to be applied to the selected group ..." (see col. 6, Ins. 55-57).

Allowable Subject Matter

Claim 8, 9, 11, 14, 23-25, 27, 30, 34, 38-40, 42-44 & 49 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

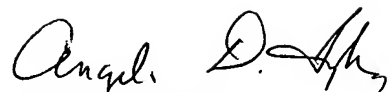
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darin R. Roberts whose telephone number is (571) 272-5558. The examiner can normally be reached on 7:30am to 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-9900.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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